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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,680

01/14/2004

Benjamin E. Morris

2015-37

4072

4897

7590

05/02/2006

ROBERT C. KAIN, JR.

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/757,680	MORRIS ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/14/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: paragraph [00142] line 2 incorrectly refers to the first retaining device as "312" instead of "310".

Appropriate correction is required.

Claim Objections

2. **Claim 15** is objected to because of the following informalities: minor inconsistency. Claim 15 recites "said actuator sleeve" in line 2 and line 3 of the claim. In the independent claim, this structure is referred to as the "actuation sleeve". Since a separate "sleeve" is claimed for the proximal actuator in several claims such as claim 2, the term "actuator sleeve" should be called "actuation sleeve" in claim 15 (as it is in claim 1) in order to clarify which structural component is being referred to. Appropriate correction is required.
3. Regarding claim 15, it appears that the actuation sleeve from independent claim 1 is intended to be a claimed element. However, the actuation sleeve is not positively recited in claim 1 and therefore the proximal actuator must only be capable of attaching to such a device and actuating such a device by relative longitudinal movement. A similar situation appears in claims 17, 26, 27, 33, 34, 47, and 48.
4. If the actuation sleeve is not intended to be a claimed element, as indicated in claim 1, a change in the wording of claim 15 is suggested in order to clear up any confusion regarding claimed elements of the device.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-10, 15-27, 32-34, and 39-48** are rejected under 35 U.S.C. 102(b) as being anticipated by Forrer (U.S. 4,576,529). Forrer discloses an actuator that is removably attachable to an elongated actuation sleeve. The actuator comprises a first retaining device (1) removably attachable to a first section of an actuation sleeve and a second retaining device (1') that is removably attachable to a second section of an actuation sleeve. The second retaining device is moveable relative to the first retaining device such that a medical device is actuated (Fig. 1a-3, and col. 2 lines 21-29). The actuation sleeve, and in later claims, an expandable frame, is not positively recited. The device must only be capable of attaching to such an actuation sleeve and actuate it by relative lateral movement. The actuator disclosed by Forrer has two retaining members that move laterally relative to each other.

7. Regarding **claim 16**, Forrer discloses an actuator that is removably attachable to first and second movable members that move longitudinally with respect to each other. The actuator comprises a first retaining device (1) removably attachable to the first movable member and a second retaining device (1') that is removably attachable to the

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second movable member. The second retaining device is moveable relative to the first retaining device.

8. Regarding **claim 18**, Forrer discloses a deployment handle removably attachable to an expandable device, the expandable device being an expandable frame, the deployment handle comprising a first retaining device and a second retaining device which are movable relative to each other such that the expandable frame is opened and closed. The clamping device disclosed by Forrer is capable of attaching to an expandable frame device and has all of the positively recited structural limitations of the claim.

9. Regarding **claim 32**, Forrer discloses a deployment handle removably attachable to an expandable device, the deployment handle comprising, a grip portion (20) including a sleeve (6), a first retaining device (1) affixed to the sleeve and removable attachable to an actuation sleeve, a sliding member (14) with a first end positionable through the aperture of the sleeve, a second retaining device (1') affixed to the second end of the sliding member and removably attachable to an actuation sleeve, and a control actuator (col. 2 lines 57-60) movably engaging the first end of the sliding member within the aperture such that the control actuator moves the second retaining member from a first position to a second position relative to the first retaining device (col. 1 lines 34-41).

10. Regarding **claim 39**, Forrer discloses the invention substantially as stated above, the handle being attachable to an expandable device. The device may include a wire member and an actuation sleeve slidably disposed about the wire member. When the

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second retaining device is moved relative to the first restraining device, the actuation sleeve would slide over the wire member and the expandable frame would open and close.

11. Regarding **claims 2, 19, and 40**, Forrer discloses a grip portion (20) having a sleeve (6) defining an aperture, wherein the first retaining device is affixed to the sleeve (Fig. 3).

12. Regarding **claims 3, 20, and 41**, Forrer discloses a sliding member (14) that has a first end that is positionable through the aperture of the sleeve.

13. Regarding **claims 4, 21, and 42**, the second retaining device is affixed to the second end of the sliding member (col. 1 lines 37-41).

14. Regarding **claims 5, 6, 22, 23, 43, and 44**, the first end of the sliding member (14) is threaded and the proximal actuator further comprises a control actuator (col. 2 lines 51-59 and col. 1 lines 37-41) moveably engaging the threaded first end of the sliding member within the aperture, such that the control actuator moves the second retaining member from a first to a second position relative to the first retaining member.

15. Regarding **claims 7, 24, and 45**, the first retaining device is in a fixed position (col. 1 lines 37-41). Forrer discloses that one or both of the jaw members are movable backward and forward as either one or both of the jaw members are threaded to engage with the rotatable spindle.

16. Regarding **claims 8, 9, 25, and 46**, the second retaining device is longitudinally movable from a first position to a second position relative to the first retaining member.

17. Regarding **claim 10**, the actuator is mounted over a guide wire (9).

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18. Regarding **claims 15 and 17**, an actuation sleeve and a wire can be retained in the retaining members. The structure of the wire and the actuation sleeve is not positively claimed in claim 1, rather the device must be capable of receiving such a device and actuating it by relative lateral movement.

19. Regarding **claims 26, 27, 33, 34, 47, and 48**, the device disclosed by Forrer meets all of the structural limitations positively recited in claims from which claims 26, 27, 33, 34, 47, and 48 depend. Furthermore, Forrer is capable of opening and closing an expandable frame by virtue of the relative lateral movement of the first and second retaining devices. A medical device used to control an expandable frame wherein relative lateral movement of two members causes the configuration of the frame to change can be positioned in the retaining members of the Forrer device and actuated.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. **Claims 11-14, 28-31, 35-38, and 49-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Forrer in view of Grover et al. (U.S. 6,193,125). Forrer discloses retaining devices comprising two legs formed by slot (3) that are fixed together with a clamping screw (4). The retaining devices each have an alignment

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indicator comprising the channel defined by aperture (2) (see Fig. 1a). Forrer fails to disclose that the first and second retaining devices are spring loaded clips.

22. However, Grover et al. discloses that it is old and well known in the art to include spring loaded clips (col. 4 lines 37-44 and col. 1 lines 61-col. 2 line 3) that hold a tool and could hold an actuation sleeve (12) in place after it is connected to a device holder. The spring loaded clips allow for rapid entry of tools into the support and securing of the tool. Grover et al. further discloses that the spring loaded clips provide a means for automatically locking the tool into the holder with the same motion used to insert it and automatically unlocking the tool with the same motion used to remove it (col. 4 lines 36-40). The two legs disclosed by Forrer could be changed to spring loaded clip assemblies so that the clamping screw would not be needed in order to lock the device into the clamp assembly after it has been placed in channel (2). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Forrer to substitute a spring loaded clip, made obvious by Grover et al., for the clamping screw assembly in order to gain the advantage of being able to lock the tool into the holder with the same motion used to insert it.

Claims 11-14, 28-31, 35-38, and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Weber et al. (U.S. 6,743,185). Freeman discloses the invention substantially as stated above, but fails to disclose that the first and second retaining devices are spring loaded clips. Freeman further fails to disclose that the first spring loaded clip comprises a first alignment indicator and the second spring loaded clip comprises a second alignment indicator.

However, Weber et al. discloses that it is old and well known in the art to include resilient clips that hold an actuation sleeve (12) in place after it is connected to a handle assembly. Spring loaded clips are a form of resilient clips and the two are being considered equivalent means to hold the actuation sleeve within the retaining devices. The resilient clips (32a, 32b) disclosed by Weber would reduce the number of parts needed for the second retaining member from a thumbscrew cap, thumbscrew, and cable clamp, to a single resilient clip. This mechanism could also be used in the first retaining member as an equivalent means of attaching the actuation sleeve. Weber et al. further discloses alignment indicators (channels 30a, 30b) which helps position the sleeve. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Freeman to substitute a resilient clip, such as a spring loaded clip, made obvious by Weber et al. for the thumbscrew assembly and the threaded attachment used by Freeman in order to reduce the number of parts and therefore the expense of the instrument. Including the alignment indicators, channels 30a and 30b, would also ensure that the actuation sleeve is properly aligned within the retaining devices.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art shows medical devices, including devices with expandable frames, being actuated by different actuator and handle assemblies

wherein relative lateral movement actuates the device. The clamping device disclosed by Ferror and explained above is capable of actuating medical devices.

U.S. 4,084,594 Mosier

U.S. 4,245,638 Lebeck et al.

U.S. 6,074,408 Freeman

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS


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SUPERVISORY PATENT EXAMINER
2/29/06